HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
Serving Medical Products Distributors Since 1902

Dockets and Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 21 CFR Parts 203 and 205: Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administration Procedures

October 25, 2000

Dear Sir or Madam:

On behalf of the Health Industry Distributors Association (HIDA), I am writing to register our opposition to the implementation of Section 503(e)(1)(A) of the Prescription Drug Marketing Act of 1987 (PDMA), which we believe would require extensive and unnecessary paperwork from secondary wholesalers of prescription drugs. This requirement was elaborated as a Final Rule in the December 3, 1999 *Federal Register* (64 FR 67720).

Founded in 1902, HIDA is the national trade association representing medical products distributors who serve the nation's long term care, hospital, imaging, and physician/ alternate care markets.

In a letter to the Food and Drug Administration dated April 25, 2000, HIDA supported a request for a Stay of Action filed on March 29, 2000 from the Pharmaceutical Distributors Association. We are pleased that the Stay of Action was granted and we applaud the FDA for soliciting public input on this critical issue.

HIDA believes that the Final Rule unnecessarily targets secondary prescription drug wholesalers by requiring them to provide extensive drug pedigree information, including documentation of all prior sales, purchases, or trades when they resell a prescription drug—even those purchased from Authorized Distributors of Record. This represents a substantial burden on secondary distributors because systems are not in place to provide the necessary data to them.

Furthermore, the affected distributors are typically small and mid-size firms that prescription drug manufacturers do not designate as Authorized Distributors for economic reasons. If it is implemented, the Final Rule will decrease competition and lead to higher prescription drug costs for low-volume buyers such as physicians who maintain small prescription drug stocks, and drug repackaging firms. These buyers rarely purchase in bulk quantities sufficient to qualify for large volume discounts offered by Authorized Distributors of Record. Only secondary distributors are in a position to offer discounts to these smaller markets.

Finally, HIDA is not aware of health or safety issues that would be protected by this Final Rule.

In response to the questions posed in the September 19, 2000 *Federal Register* (65 FR 56480), HIDA would like to emphasize the following points:

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- **Accountability and Potential for Increased Risk**. HR 4301, which has 31 cosponsors in the House of Representatives, would amend this section of the PDMA and require secondary wholesalers to maintain documentation that certifies that the drugs were first purchased by an Authorized Distributor of Record. Current law permits both FDA and State inspectors to verify the accuracy of such documentation, and subjects violators to criminal penalties. HIDA believes that the current regulations sufficiently prevent introduction of expired, counterfeit, misbranded or otherwise unsuitable drugs from entering the marketplace.

- **Shifting Pedigree Responsibilities to Authorized Distributors of Record.** HIDA opposes this suggestion because once again, it creates unnecessary paperwork that shows little, if any, health or safety benefits. As with secondary distributors, this proposed requirement would place an additional burden on the Authorized Distributors of Record. We foresee a logistical nightmare for these distributors because of the volume and frequency of their purchases, which generally involve numerous lot numbers and dosage forms and amounts that we expect would have to be kept physically separate in order to meet stringent pedigree requirements. In addition, distributors already maintain this data in their records, which are subject to FDA and State inspection and penalties. Maintaining this accountability in a physical sense would be overwhelming.

- **Using Sales Volume to Determine an Ongoing Relationship Between Drug Manufacturers and Distributors.** This is precisely what Congress intended when it passed the PDMA. We support using this criterion to determine who may be classified as an Authorized Distributor of Record. Depending on the volume that the FDA selects to determine an ongoing relationship (and we assume, classification as an Authorized Distributor of Record), this would increase the overall number of Authorized Distributors. HIDA speculates that this might, eventually, force manufacturers to lower their purchase prices, allowing distributors to pass savings to customers and patients.

We urge FDA to revisit this Final Rule and replace it with sound health, safety, and workable business practices.

Please feel free to contact me at 703-838-6109 if you have any questions or comments about HIDA's position. Thank you for your consideration.

Sincerely,

Ruth Ann C. Kaiser

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Director, Government Relations

cc: Matthew J. Rowan, President and CEO
Dan Moskowitz, Chairman
Steven Skoronski, Chairman-elect

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